

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ABRAXIS BIOSCIENCE, INC.,

Plaintiff,

$$V.$$

NAVINTA LLC,

Defendant.

Civil Action No. 07-1251 (JAP)

OPINION

PISANO, District Judge.

This is a patent infringement action brought by Plaintiff, Abraxis BioScience, Inc. (“Abraxis” or “Plaintiff”), against Navinta LLC (“Navinta” or “Defendant”). Presently before the Court is a motion by Defendant to dismiss this action under Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction. Defendant contends that Plaintiff did not possess the requisite title to any of the three patents asserted in this action when the Complaint was filed on March 15, 2007, and, therefore, lacked standing to sue for patent infringement. Also before the Court is a motion by Abraxis to join APP Pharmaceuticals, LLC (“APP”), an assignee of the patents-in-suit, as a plaintiff. For the reasons set forth below, Defendant’s motion to dismiss is denied and Plaintiff’s motion for joinder is granted.

I. BACKGROUND

1. The Parties

Plaintiff is the manufacturer an injectable drug with the brand name Naropin that is

composed of ropivacaine hydrochloride. Naropin is used medically as an anesthesia as well as for pain management. At issue in this case are three patents relating to the drug, patent numbers 4,870,086 (“the ’086 Patent”), 5,670,524 (“the ’524 Patent”), and 5,834,489 (“the ’489 Patent”). According to the amended complaint, at the time the amended complaint was filed, “by way of assignment, Abraxis own[ed] all rights, title and interest” in these patents, “including the right to sue and recover for patent infringement.” Amended Complaint ¶ 11.

Defendant is a generic drug manufacturer. Defendant filed, pursuant to 21 U.S.C. § 355(j), an Abbreviated New Drug Application (“ANDA”) No. 78-601 with the United States Food and Drug Administration (“FDA”), seeking approval to market ropivacaine hydrochloride for anesthetic purposes. On March 15, 2007, Plaintiff brought the present suit challenging Defendant’s ANDA. On November 20, 2007, Plaintiff filed an amended complaint, alleging that Defendant’s proposed use of ropivacaine hydrochloride as set forth in its ANDA would infringe upon the ’086, ’524, and ’489 Patents.

2. Plaintiff’s Acquisition of the Patents

The patents at issue in this action were acquired by Abraxis from a third party, AstraZeneca UK Limited (“AZ-UK”), as part of a much larger \$350 million transaction. By way of this transaction Abraxis acquired the rights to market, sell and license eight pharmaceutical products in the United States as well as all the rights to patents, including the asserted patents, and other intellectual property protecting those eight products.

On April 26, 2006, prior to the filing of this lawsuit, Abraxis entered into an Asset Purchase Agreement (“APA”) pursuant to which AZ-UK was to, or was to “cause one or more of its Affiliates to,” transfer to Plaintiff “all of the right, title and interest of [AZ-UK] and its

Affiliates in” certain assets that included the ’086, ’524, and ’489 Patents. APA at 15, attached as Exhibit B to the Declaration of Benjamin Lehberger (“Lehberger Decl.”). This transfer was to take place at and as of the “Effective Time,” which by application of the definition in the APA was June 28, 2006.¹ Declaration of Bruce Wendel (“Wendel Decl.”) ¶ 6.

On June 28, 2006, as contemplated by the APA, AZ-UK and Abraxis executed an IP Assignment Agreement (“IP Agreement”). *See* IP Agreement attached to Wendel Decl. at Ex. B. This agreement provided that AZ-UK “hereby sells, assigns, conveys and transfers” to Abraxis, for Abraxis’s “sole and exclusive use and enjoyment,” all of AZ-UK’s “right, title and interest in and to,” the “Transferred Patent Rights” as well as other intellectual property. *Id.* Ex B at 1. Among the “Transferred Patent Rights” identified in the IP Agreement are the ’086, ’524, and ’489 Patents. *Id.* Ex. B at Schedule A.

The parties do not appear to dispute that at the time the IP Assignment Agreement was executed, two third parties, Astra Lakemedel (“Astra L”) (a corporate affiliate of AZ-UK) and AstraZeneca AB (“AZ-AB”) (a subsidiary of AZ-UK), were assignees of record for the ’086 Patent, and the ’524, and ’489 Patents, respectively.² *See* Wendel Decl. ¶ 11. However, it was not until early 2007, several months after execution of the IP Agreement, that Abraxis learned of

¹The APA defines “Effective Time” as “12:01 a.m., New York time on the Closing Date.” Lehberger Decl., Ex. A at 5. “Closing Date” is defined as “July 31, 2006 or such earlier date as the parties shall mutually agree” *Id.* 3-4. In fact, the parties agreed to close the transaction on an earlier date, namely June 28, 2006. Wendel Decl. ¶ 6.

²The named inventor of the ’086 Patent is Rune Sandberg, who in 1986 assigned the rights in his invention to Astra L, an affiliate of AZ-UK. Lehberger Decl. Ex. D. The United States Patent Office subsequently issued the ’086 Patent in 1989. The named inventor for the ’524 and ’489 Patents is Arne Torsten Eek, who assigned his rights in these patents to AB Astra in 1994. *Id.* Ex. E. The United States Patent Office subsequently issued the ’524 Patent in 1997 and the ’489 Patent in 1998. Later, in 2000, AB Astra assigned its rights in the ’524 and ’489 Patents to AZ-AB, a subsidiary of AZ-UK. *Id.* Ex. F.

the possibility that AZ-AB and Astra L had an ownership interest in the patents. *Id.* As a result, and in order to ensure that Abraxis received the full set of rights in the '086, '524, and '489 Patents as agreed to by the parties in the APA and IP Agreement, Abraxis requested that AZ-UK enter into assignment agreements with these affiliates as contemplated by the APA. By agreement executed on or about March 15, 2007, AZ-AB assigned all of its rights in the '524 and '489 Patents to AZ-UK, *see* Wendel Decl. Ex. C, and Astra L assigned all of its right in the '086 Patent to AZ-UK, *see id.* Ex. D.

Thereafter, on or about November 12, 2007, AZ-UK and Abraxis executed an Intellectual Property Assignment Agreement. This agreement

confirm[ed] the sale, assignment and transfer to Abraxis, for Abraxis' sole and exclusive use and enjoyment, of all of AZ-UK's right, title and interest in and to [the '086, '524, and '489 Patents] and the patent applications therefor pursuant to the Asset Purchase Agreement and further sells, assigns, conveys and transfers to Abraxis . . . all of AZ-UK's right, title and interest, if any, in and to [the '086, '524, and '489 Patents] and the patent applications therefor pursuant to the Asset Purchase Agreement.

Wendel Decl. Ex. E at 2. The Abraxis and AZ-UK executed this agreement in order to

remove any doubt that Abraxis owns all right, title, and interest, both legal and equitable, to [the '086, '524, and '489 Patents] and the patent applications therefore, including the right to sue and recover for patent infringement, and has owned all such right, title and interest no later than June 28, 2006.

Wendel Decl. Ex. E at 1.

II. DISCUSSION

1. Navinta's Motion to Dismiss

A. Standard of Review under Rule 12(b)(1)

Because standing is jurisdictional, a motion to dismiss based on lack of standing should

be brought under Federal Rule of Civil Procedure 12(b)(1). *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007). A party may assert its jurisdictional challenge under Rule 12(b)(1) by attacking the complaint on its face or making a factual challenge separate from any pleading. In the instant case, the challenge is factual, *i.e.*, attacking “the existence of subject matter jurisdiction in fact, quite apart from any pleadings.” *Mortensen v. First Fed. Sav. and Loan Ass’n*, 549 F.2d 884, 891 (3d Cir. 1977). As such, when considering the motion, the Court need not attach “presumptive truthfulness” to the allegations of the non-moving party, and “the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims.” *Id.* In adjudicating a factual 12(b)(1) challenge, a court may consider affidavits, depositions, and testimony to resolve factual issues, and weigh the evidence to satisfy itself as to the existence of its power to hear the case. *Iwanowa v. Ford Motor Co.*, 67 F. Supp. 2d 424, 438 (D.N.J. 1999).

B. Analysis

Defendant argues that Plaintiff did not obtain any rights or title to any of the asserted patents from AZ-UK until the Intellectual Property Assignment Agreement between Abraxis and AZ-UK was executed in November 2007, several months after the Complaint in this action had been filed. As a result, Defendant asserts that Plaintiff lacked standing to sue and now moves to dismiss the suit. Plaintiff, on the other hand, argues that it had both legal and equitable title to the patents at the time this action was brought and, therefore, had standing to bring this case.

“Only a patent owner or an exclusive licensee can have constitutional standing to bring an infringement suit[.]” *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1367 (Fed. Cir. 2008). The burden of establishing standing to bring an action for patent infringement falls upon the

plaintiff. *Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005). To meet its burden, a plaintiff must establish that it held enforceable title to the patent at the inception of the lawsuit. *Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1309 (Fed. Cir. 2003).

If the plaintiff lacks standing to sue, the case must be dismissed under 28 U.S.C. § 1338(a) for lack of subject matter jurisdiction. *See Fieldturf, Inc. v. Southwest Rec. Indus., Inc.*, 357 F.3d 1266, 1268 (Fed. Cir. 2004). “In the area of patent infringement ... if the original plaintiff lacked ... initial standing, the suit must be dismissed, and the jurisdictional defect cannot be cured by the addition of a party with standing.” *Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198, 1203 (Fed. Cir. 2005). Such a dismissal for lack of standing is ordinarily without prejudice. *H.R. Techs., Inc. v. Astechologies, Inc.*, 275 F.3d 1378, 1385 (Fed. Cir. 2002).

To substantiate a claim of patent ownership and, consequently, standing, a plaintiff who is not the original patentee “must produce a written instrument documenting the transfer of [ownership].” *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1250 (Fed. Cir. 2000). Here, the parties have produced a series of documents which track the chain of title for the patents. These documents show, ultimately, that AZ-UK transferred ownership of the patents to Abraxis. However, the dispute here is not *whether* the documents transfer title to Abraxis, but rather, the dispute at the center of the instant motion is *when* title was actually transferred.

Plaintiff contends that by way of execution of the series of documents described above, Abraxis obtained legal title to the patents as of June 28, 2006, including the right to sue for acts of infringement after that date. According to Plaintiff, Abraxis and AZ-UK structured the transaction so that these documents -- the APA, IP Agreement, and the March 2007 assignments -- “constituted a single integrated agreement granting Abraxis legal title to the patents as of the

June 28, 2006 closing date.” Pl. Brf. at 13.³ In Plaintiff’s view, the March 2007 assignments from Astra L and AZ-AB operated to retroactively to vest title to the patents in AZ-UK as of June 28, 2006 – the date of execution of the IP Assignment Agreement and the “Effective Time” as defined in the APA. As such, Plaintiff asserts that the IP Agreement then operated to transfer title to the patents to Abraxis at the “Effective Time” as well. Thus, according to Plaintiff, the three documents taken together, regardless of their order of execution, operated to transfer ownership of the patents to Abraxis as of June 28, 2006. Plaintiff contends that this interpretation of the documents was confirmed by the parties in the Intellectual Property Assignment Agreement in November 2007.

Defendant, on the other hand, asserts that Plaintiff’s argument is flawed because the March 2007 assignments from Astra L and AZ-AB do not expressly state that they are retroactive. According to Defendant, these agreements vested title as well as the right to sue for future -- not past -- infringement in AZ-UK only as of March 15, 2007, the date they were executed. Moreover, Defendant contends that title did not actually transfer to Abraxis until November 2007, upon execution of the Intellectual Property Assignment Agreement.

As Abraxis points out, the parties to a transaction can expressly provide that a written contract may be deemed effective on a date other than the actual execution date. *Viacom Intern. Inc. v. Tandem Productions, Inc.*, 368 F.Supp. 1264, 1270 (S.D.N.Y. 1974) (“When a written contract provides that it shall be effective “as of” an earlier date, it generally is retroactive to the earlier date.”) (citing *Mutual Life Ins. Co. v. Hurni Packing Co.*, 263 U.S. 167, 175-176, 44 S.Ct.

³Plaintiff offers alternative arguments with respect to the operation of the relevant documents as well as the existence of equitable standing. In light of Court’s decision on this first issue, it not need reach those alternative arguments.

90, 68 L.Ed. 235 (1923); *Brewer v. National Surety Corp.*, 169 F.2d 926, 928 (10 Cir. 1948); *Matthews v. Jeremiah Burns, Inc.*, 205 Misc. 1006, 1013, 129 N.Y.S.2d 841 (Sup. Ct. N.Y. 1954)). Under the APA, “the effectiveness of the documents, agreements, opinions and certificates delivered in accordance with [the APA], and the consummation of the transactions contemplated [by the APA]” were “deemed to occur at the Effective Time,” *i.e.*, June 28, 2006. *See* APA § 3.1. Given these provisions, it is notable that each March 2007 assignment agreement recognized that the assignment was being undertaken in furtherance of the “[APA], dated as of April 26, 2006, . . . pursuant to which [AZ-UK] agreed to sell to [Abraxis] and [Abraxis] agreed to purchase from [AZ-UK] the Transferred Assets, all as more particularly set forth in the [APA]” and to allow AZ-UK “to further convey to [Abraxis]” the ’086, ’524, and ’489 Patents. Wendel Decl. at Ex. C and D.

Although Defendant is correct that Astra L and AZ-AB were not parties to the APA, neither were they complete strangers to that transaction. They were, respectively, a corporate affiliate and subsidiary of AZ-UK, and each of the March 2007 agreements expressly recognize that they are “affiliate[s] of the Transferee.” So while Astra L and AZ-AB may not have been bound by the terms of the APA, given their relationship to the transaction between Abraxis and AZ-UK, the Court finds that their express recognition of the APA in the March 2007 assignments is significant -- it evinces their intent that their transfer of the patents to AZ-UK be in accordance with the terms of that agreement, *i.e.*, retroactive to June 28, 2006. Given this retroactive effect, the IP Agreement would then operate to transfer title from AZ-UK to Abraxis as of that date as well. Accordingly, the Court finds that the relevant documents, taken as a whole, effectively transferred rights in the patent to Abraxis as of June 28, 2006. Therefore, Plaintiff did not lack

standing at the time if filed the instant lawsuit, and Defendant's motion to dismiss for lack of standing is denied.

2. Plaintiff's Motion for Joinder

In November 2007, Plaintiff divided its business and operations into two companies. Declaration of Richard E. Maroun ¶ 2.⁴ It continued its oncology and research business as "Abraxis Bioscience," and formed a new company, APP, to focus on "hospital-based business." *Id.* ¶ 3. At that time, Abraxis and APP executed a Separation and Distribution Agreement in which Abraxis agreed that it would transfer to APP certain patents, including the '086, '524, and '489 Patents. *Id.* ¶ 3-4. Shortly thereafter, on December 5, 2008, Abraxis executed an assignment of these patents to APP and, therefore, APP is now the legal owner of the patents-in-suit.

Abraxis has moved under Federal Rule of Civil Procedure 25(c) to join APP as a plaintiff in this action. Under FRCP 25, "[i]f an interest is transferred, the action may be continued by or against the original party unless the court, on motion, orders the transferee to be substituted in the action or joined with the original party." Fed.R.Civ.P. 25(c). Because a joinder or substitution under Rule 25 does not alter the substantive rights of the parties, the decision whether to join or substitute a party lies within the discretion of the district court. *Luxliner P.L. Export, Co. v. RDI/Luxliner, Inc.*, 13 F.3d 69, 71-72 (3d Cir.1993). A joinder or substitution under Rule 25 is appropriate when a district court, in the exercise of its discretion, finds that such joinder or substitution would facilitate the conduct of a case. *Id.* Generally, Rule 25 allows the case to be

⁴This declaration was submitted with Plaintiff's sur-reply in connection with Defendant's motion to dismiss. Because Defendant had raised an entirely new issue in its reply concerning the potential assignment of the patents to APP, the Court accepted and considered Plaintiff's sur-reply.

continued against the original party, and any judgment will be binding on the successor in interest, even if the successor is not named in the lawsuit. *Id.* at 71.

Navinta has taken varying positions with regard to Abraxis maintaining this suit in light of the transfer of the patents from Abraxis to APP. Defendant first raised the issue in its reply brief filed in connection with its motion to dismiss (which was filed prior to the actual assignment of the patents from Abraxis to APP), in which Defendant mistakenly asserted that Plaintiff no longer owned the patents at issue in this case. As a result, Defendant argued at that time that because “Abraxis has no personal stake in the outcome of the lawsuit,” the suit should be dismissed. Reply at 9-10. Now, after the assignment of the patents has actually been effected and Abraxis moves to join APP in this litigation, Navinta opposes that motion, raising the same standing arguments it raised in its motion to dismiss, and further asserting that joinder of APP as a plaintiff is not necessary because the lawsuit can proceed in the name of the original party under Rule 25(c). Def. Opp. at 4. Navinta also claims that the addition of APP as a Plaintiff will delay resolution of this suit.

In the “Assignment of Patents” dated December 5, 2008, Abraxis assigned to APP all “right title and interest in and to [the ’086, ’524, and ’489 Patents]. . .” Declaration of Anthony Gruppuso, Ex. B. Included in the assignment were “all claims and causes of action against third parties (including the right to sue) for infringement, past, present and future.” *Id.* Accordingly, it is appropriate for the Court to join APP as the real party in interest in this litigation. *See General Battery Corp. v. Globe-Union, Inc.*, 100 F.R.D. 258 (D. Del. 1982) (in action seeking declaration that patent was invalid with counterclaims for patent infringement, court joined patent assignee as defendant/counterclaim plaintiff).

The Court finds no merit to Defendant's contention that the joinder of APP will somehow delay the course of this litigation. Indeed, although APP was not formally a party to this lawsuit, it appears that APP "has been providing documents, witnesses and discovery in this case to Defendant Navinta as if it were a party." Maroun Decl. ¶ 4. Also, APP's counsel has represented to the Court that APP will not serve any fact discovery requests of its own if it is joined as a co-plaintiff. Consequently, the Court finds no basis for Navinta's claim of potential delay. Plaintiff's motion for joinder is granted.

III. CONCLUSION

For the reasons above, Defendant's motion to dismiss is denied and Plaintiff's motion for joinder is granted. An appropriate Order accompanies this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: March 23, 2009